



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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M24621
PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

March 12, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert A. Brumbaugh, Sr., Owner
Robert A. Brumbaugh, Jr., Owner
Brumbaugh Farms
RD # 1
P.O. Box 108
Martinsburg, PA 16662

Gentlemen:

On February 24, 1999 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your dairy farm located in Martinsburg, PA, in response to a United States Department of Agriculture (USDA) report regarding a violative drug residue in a cow you offered for sale for slaughter for human food. Additional investigation by the FDA at [REDACTED] and at your veterinarian, [REDACTED], has revealed serious violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about December 9, 1998, Robert A. Brumbaugh, Sr. offered a cow, back tags #332 and #5616 and ear tag #23VPV3316, for sale for slaughter as human food at [REDACTED]. The subject cow was purchased by [REDACTED], [REDACTED] on or about December 9, 1998 and was slaughtered for food on or about December 10, 1998. United States Department of Agriculture (USDA) testing revealed the presence of 0.31 ppm (parts per million) penicillin in the kidney tissue of the animal. This is considered to be a violative tissue residue since the tolerance for penicillin in edible bovine tissue is 0.05 ppm. The presence of penicillin in the edible kidney tissue from your animal at the concentration level detected renders the food from the animal to be adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an

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adequate system to assure that animals have been treated with drugs which have been approved for use in those species; to assure that drugs are used in a manner not contrary to the directions contained in the labeling; and to assure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

Our inspection determined that you treated the subject cow with penicillin without veterinary oversight because her calf was aborted and she retained the placenta. [REDACTED] was not informed of the medication status of the subject cow when you delivered it for sale for slaughter.

The FDA is also aware of another medicated cow which you delivered for sale for slaughter for food at [REDACTED] on or about April 6, 1998. The subject cow, back tag #8181, was slaughtered for human food at [REDACTED] on or about April 8, 1998 and subsequent USDA testing revealed violative sulfadimethoxine residues in the animal's liver and muscle tissues. During a Pennsylvania Department of Agriculture (PDA) inspection of your farm on May 18, 1998 you signed an affidavit indicating that you did not inform [REDACTED] of the medication status of this animal.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 days

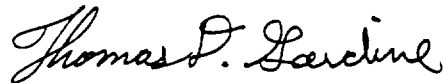
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of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violation and prevent its recurrence.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

jci

cc: Dr. John I. Enck, Director
PA Department of Agriculture
Bureau of Animal Health and Diagnostic Services (BAHDS)
2301 North Cameron Street
Harrisburg, PA 17120

cc: Food Safety and Inspection Service (FSIS)
106 South 15th Street
Suite 904
Omaha, Nebraska 68102
Attention: Residue Staff